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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,801	09/17/2003	Torben Halkier	4614-0120P	3913

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
06/27/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/664,801	HALKIER ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58,59,61,62 and 67-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58,59,61,62 and 67-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 16 April 2007 has been entered in full. Claims 1-57, 60 and 63-66 are canceled. New claims 71-74 were added. Claims 58, 59, 61, 62 and 67-74 are pending and under examination.

Withdrawn Objections And/Or Rejections

The rejection to claims 67-70 under 35 U.S.C. 112, first paragraph, written description (new matter), as set forth at pages 5-6 of the previous Office Action (15 December 2006), is *withdrawn* in view of the amendment (16 April 2007).

The rejection to claims 58, 59, 61, 62, 65-70 under 35 U.S.C. 103(a) as being unpatentable over Anderson, US Patent No. 6,740,522 B2 in view of Tsukii *et al.,* Biochemical and Biophysical Research Communications 246:337-341 (1998), as set forth at pages 2-5 of the previous Office Action (15 December 2006), is *withdrawn* in view of Applicant's argument regarding the Anderson reference (16 April 2007).

Claim Rejections-35 USC § 112, First Paragraph, Scope of Enablement

Claims 58, 59, 61, 67, 69, 70, (and new claims 72 and 73) remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for down-regulation of autologous OPGL or treating, ameliorating a disease in an individual in need thereof comprising administering **immunogenic agent as OPGL polypeptide or a OPGL nucleic acid**

does not reasonably provide enablement for:

a method for down-regulation of autologous OPGL or treating, ameliorating a disease in an individual in need thereof comprising administering **an immunogenic agent or a non-pathogenic organism.**

The basis for this rejection is set forth at pages 6-10 of the previous Office Action (15 December 2006).

Applicant cites *In re Wands*, which the Examiner takes no issue with. Applicant directs the Examiner's attention to pages 42-61 of the instant specification. Applicant argues that the specification provides a description of the kinds of polypeptides, nucleic acids and nonpathogenic microorganisms useful as immunogenic OPGL agents in the presently claimed invention. Applicant points out that general protocols for making and using immunogenic agents are known in the immunology/biotechnology field and regularly practiced by POSITAs. Applicant argues that the instant claims have been amended to recite the presentation of immunogenic OPGL to the immune system, thereby obviating the rejection of administration of a vaccine.

Applicant's arguments have been fully considered but are not deemed persuasive. The scope enablement issue is judged against the well-established Wands factors, as recited in the previous office action. Pages 42-61, as cited by Applicant, teach a concept of immunizing individuals against the OPGL antigen in order to reduce osteoclast activity. The specification teaches that the preferred way of obtaining such an immunization is to use modified versions of OPGL. Thus, the specification *teaches the use of OPGL polypeptides, OPGL analogues, OPGL nucleic acids as immunogenic*

agents, not any immunogenic agent. The specification fails to teach how to make and use "any immunogenic agent" to induce an immune response and down-regulate autologous OPGL in an individual. The term "an immunogenic agent" encompasses a large genus. The instant specification fails to indicate that a representative number of structurally related compounds are disclosed and therefore, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claim and would not know how to make them. The specification fails to disclose examples demonstrating that upon administering any immunogenic agent, antibodies against the immunogenic agent will result in *in vivo* down-regulation solely of endogenous OPGL activity.

Secondly, the issue is not whether the specification teaches how to make and/or use a OPGL polypeptide vaccine or nucleic acid encoding OPGL vaccine, the issue is whether the instant specification teaches how to administer a non-pathogenic organism such as vaccinia or pox virus comprising OPGL as a vaccine. The examples from the specification teach the construction of OPGL protein vaccines. However, it could not be predicted that the instant data presented in the specification would be in any way correlative with administration of non-pathogenic organism comprising OPGL. The Examiner submitted reference that teach the problems associated with the use of live bacterial carriers such as reversion to virulence, horizontal gene transfer, host genetic factor, immune responses, accommodation of heterologous DNA, safety concerns, lyophilization and/or host cell range of vaccine vectors. For example, Dudek et al. (reference of record, Virology, 344:230-239, 2006). teach that poxviruses are strong

candidates for vaccine vectors but concerns about their safety still remain. The quantity of experimentation for the instant invention is not routine and the specification has provided little guidance on how to make and/or use the instant invention in a safe and effective manner.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections-35 USC § 112, First Paragraph, Written Description

Claims 58, 59, 61, 67, 69-70 (and new claims 72 and 73) remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The basis for this rejection is set forth at pages 10-11 of the previous Office Action (15 June 2001).

Applicant calls the Examiner's attention to pages to 42-61 of the instant specification. Applicant argues that the specification provides a description of the kinds of polypeptides, nucleic acids and nonpathogenic microorganisms useful as immunogenic OPGL agents in the presently claimed invention. Applicant argues that the disclosure surveys methods for identifying, making and using the claimed OPGL immunogenic agents by expression description, reference to published texts and by example. In addition, the Sequence Listing of the present application discloses the exact nucleic and amino acid sequences for a substantial number of OPGL immunogens useful in the presently claimed invention. Applicant submits that the disclosure amounts to a considerable number of OPGL immunogen species in precise

structural and physical property terms. Applicant argues that the specification conveys to a POSITA that Applicants had possession of the presently claimed OPGL immunogen genus at the time of filing.

Applicant's arguments have been fully considered but are not deemed persuasive. Pages 42-61, as cited by Applicant, teach a concept of immunizing individuals against the OPGL antigen in order to reduce osteoclast activity. The specification teaches that the preferred way of obtaining such an immunization is to use modified versions of OPGL. As was stated above, the specification teaches the use of OPGL polypeptides, OPGL analogues, OPGL nucleic acids as immunogenic agents, **not any immunogenic agent**. There is insufficient descriptive support for the genus "an immunogenic agent". As was stated in the last Office Action, an immunogenic agent can encompass, lipids, antibodies, nucleic acids, chemical analogs, biomolecules, macromolecules, etc. The instant method requires the use of undisclosed agents. The specification does not demonstrate possession of the instant process steps, which require the use of undisclosed immunogenic agents. No structural characteristics of such immunogenic agent are provided, nor is there any indication that applicant had possession of any immunogenic agent. The instant claims are drawn to a genus of immunogenic agents based entirely on function.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58, 59, 61, 62, 65-70 (and new claims 72 and 74) remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 15 of U.S. Patent No. 6,645,500 B1 in view of Tsukii *et al.*, Biochemical and Biophysical Research Communications 246:337-341 (1998) (reference of record). The basis for this rejection is set forth at pages 11-14 of the previous Office Action (15 December 2006).

Applicant states that this rejection will be addressed upon a finding of patentable subject matter.

NEW REJECTIONS/OBJECTIONS

Claims 58, 59, 61, 62, 67-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: "**autologous** immunogenic" (claims 58, 59, 61, 62, 67)

"non-pathogenic organisms (claims 69 and 72)

"Streptococcus ssp." (claim 72)

"vaccine" (claim 72)

Applicant's amendment, filed 16 April 2007, asserts that no new matter has been added but does not provide sufficient direction for the written description for the above-mentioned limitation "autologous immunogenic". The Examiner cannot locate the wording or connotation of the instant claims.

Applicant directs support to pages 29, 36 and 39 for claim 69 and page 39 for claim 72. The Examiner has located the limitations "non-pathogenic **micro**organism" (page 39, lines 10-11), "**non-pathogenic** Steptococcus spp." (page 39, line 16) and vacc**inia** (page 39, line 27).

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The specification does not provide direction for the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58, 59, 61, 69-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58, 59, 61, 69-74 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The instant claims fail to teach how effecting presentation to the immune system is accomplished. For example, is the method accomplished via vaccination, immunization and/or administering?

Claim 69 is indefinite for the following reasons. Claim 69 recites, "the method according to claim 62 wherein said immunogenic agent is presented to the immune system of said subject as a peptide immunogen, a nucleic acid immunogen and/or a non-pathogenic organism. Claim 62, which recites, "wherein said immunogenic agent is an OPGL polypeptide comprised of the sequence set forth in SEQ ID NO:2. Claim 69 is indefinite because it is unclear if the nucleic acid immunogen recited in claim 69 is a

nucleic acid encoding OPGL polypeptide SEQ ID NO:2. It is unclear if the non-pathogenic organism recited in claim 69 comprises an OPGL polypeptide SEQ ID NO:2.

Claim 69 is indefinite because it recites "wherein said immunogenic agent is ....a non-pathogenic organism". Claim 69 depends from claims that recite, "an autologous immunogenic agent". The specification fails to teach the definition of "an autologous non-pathogenic organism". Thus the metes and bounds of this claim cannot be determined.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
6/19/07

Marianne P. Allen
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6/21/07